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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,667	08/26/2003	Chengjin M. Huang	AM101193	3920
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WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			EXAMINER LE, EMILY M	
			ART UNIT	PAPER NUMBER
			1648	
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			05/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/648,667

Applicant(s)

HUANG, CHENGJIN M.

Examiner

Emily Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/22/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 11-18 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22 is/are allowed.
- 6) ☒ Claim(s) 1-10 and 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 1-22 are pending. Claims 11-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-10 and 19-22 are under examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 7 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In response to this rejection, Applicant submits that mAb 1D9 is not a name used a trade, rather, Applicant is being his/her own lexicographer by coining the claimed antibody as mAb 1D9. Applicant also submits that Applicant has provided definition of the properties that are encompassed by the claimed monoclonal antibodies. To support this submission, Applicant directs the Office's attention to Figure 1, which displays a photograph of a Western immunoblot analysis of mAb 1D9, which has a broad band of 95-100 Kd.

Applicant's submission has been considered, however, it is not found persuasive.

The Office recognizes that Applicant can be his/her own lexicographer, however, it is found that the specification has not disclosed sufficient amount of information or teachings that would allow traders or workers in the art to readily identify the claimed antibody. In the instant, the specification fails establish a sufficiently precise and definite meaning for the monoclonal antibody product. All that is provided in the specification is the following: mAb 1D9 is a monoclonal antibody that recognizes the surface protein component of the inactivated FIV, and not that of the live FIV, and that the heavy and light chains of said antibody is about 50 Kd and 25 Kd. However, beside this one biological characteristics, and general characterization on the molecular weight of the heavy and light chains, the specification has not set forth any additional insight relating to the monoclonal antibody product known as mAb 1D9. In the instant, the specification has not set forth any additional guidance that would allow a sufficiently precise identification of the product known as mAb 1D9. The specification does not contain any structural data for mAb 1D9. The complete amino acid sequence of the product known as mAb 1D9 is not provided by the specification. Nor is the amino acid sequence for the complementarity determining regions of mAb 1D9 is provided. Hence, in the absence of a definition or guidance that would allow a sufficiently precise and definite identification of the product known as mAb 1D9, the claims are rendered indefinite. See MPEP § 608.01(v)

Additionally, the Office acknowledges Applicant's assertion that monoclonal antibody 1D9 has a specific and novel binding activity, and that this should be sufficient enough to allow the skilled artisan to identify mAb 1D9; however, this is not found

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persuasive. In the instant case, Applicant has not disclosed the structural identity of the epitope that renders the alleged novel binding activity. In the absence of such disclosure, the skilled artisan would not be able to identify or recognize the monoclonal antibody noted as mAb 1D9.

5. Claims 1-6, 8-10 and 19-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to the rejection, Applicant submits that one of ordinary skill in the art would learn from the example provided in the specification that any of the numerously known starting material could be readily substituted for the illustrated formalin-treated FIV-Shiz virus to obtain the monoclonal antibody specific for the inactivated FIV-encoded glycoprotein. It is also noted that the specification discloses that the claimed monoclonal antibody may be produced by a cell line ATCC number. PTA-4837.

In response to Applicant's submission(s), Applicant is reminded that the rejection is a written description rejection, wherein the claims(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention; and not an enablement rejection, which is directed at teaching the skilled artisan how to make and use the claimed invention. The written description requirement is severable from the enablement requirement. Thus, while

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Applicant may assert to have taught the skilled artisan how to make the claimed invention, Applicant has not demonstrated or reasonable convey to the skilled artisan that Applicant is in possession of the genus of monoclonal antibodies being claimed in the instant patent application. Applicant has shown and demonstrated that Applicant is in possession of one monoclonal antibody, mAb 1D9.

As previously stated, the claims are directed to a genus of monoclonal antibodies that is specific for an epitope unique to an inactivated feline immunodeficiency virus (FIV)-encoded glycoprotein, wherein the monoclonal antibody specifically reacts with or recognizes inactivated FIV or inactivated FIV glycoprotein but does not react with or recognize live FIV or FIV glycoprotein.

To provide adequate written description and evidence of possession of a **claimed genus**, the specification must provide sufficient description of a representative number of species by i) actual reduction to practice, ii) reduction to drawings; or iii) disclosure of relevant identifying characteristics, such as disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, correlation between structure and function, and methods of making. The analysis is as follow:

i) Sufficient description of a representative number of species by actual reduction to practice: The specification only teaches of one monoclonal antibody, mAb 1D9, that is disclosed to specifically react with or recognizes inactivated FIV or inactivated FIV glycoprotein but does not react with or recognize live FIV or FIV glycoprotein. The specification does not teach of any other monoclonal antibodies

beside mAb 1D9. Hence, the specification fails to provide sufficient description of a representative number of species by actual reduction to practice.

• **ii) Sufficient description of a representative number of species by reduction to drawings:** The specification contains one drawing, Figure 1. Figure 1 sets forth the molecular weight of the heavy and light chain of mAb 1D9. No other antibodies is set forth in Figure 1. Hence, the drawing fails to provide a sufficient description of a representative number of species by reduction to drawings.

iii) Sufficient description of a representative number of species by disclosure of relevant identifying characteristics: The specification only teaches that mAb 1D9 specifically reacts with or recognizes inactivated FIV or inactivated FIV glycoprotein but does not react with or recognize live FIV or FIV glycoprotein. The specification does not set forth neither the complete or partial structure of antibodies encompassed by the genus of antibodies instantly claimed. The specification does not set forth any structural requirements or guidance relating to the claimed antibodies and the specified functional characteristic, specifically reacts with or recognizes inactivated FIV or inactivated FIV glycoprotein but does not react with or recognize live FIV or FIV glycoprotein. All that is present is the asserted functional characteristics, specifically reacts with or recognizes inactivated FIV or inactivated FIV glycoprotein but does not react with or recognize live FIV or FIV glycoprotein. However, in the absence of any structural data that relates to the asserted functional characteristic, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of compounds based on the teaching from the specification.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). And therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only a monoclonal antibody identified as mAb 1D9, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Additionally, regarding Applicant’s submission about cell line ATCC No. PTA-4837, the disclosure has been considered, however, it is found that it is not sufficient to demonstrate or convey to the skilled artisan that Applicant is in possession of the genus of monoclonal antibodies claimed. In the instant case, while this cell line may secrete mAb 1D9, however, this cell line is not specific or limited to mAb 1D9. It is noted that

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Applicant teaches is that the claimed "antibody **may be produced** from cell line deposited at the American type Culture Collection (ATCC) under Accession No. PTA-4837." [Lines 14-15, page 4; emphasis added.] In this case, PTA-4837 is not a hybridoma that is specific for the production of mAb 1D9. This cell line is a primary hybridoma that Applicant obtained by fusing Sp2/0 myeloma cells with spleen cells from BALB/c mice that has been immunized with formalin-treated feline immunodeficiency virus (FIV) preparation. Applicant teaches that in order to obtain a monoclonal antibody producing hybridoma, this primary hybridoma must be screened for specific reactivity with formalin-treated FIV. [Lines 5-12, page 4; and lines 18-28, page 6.] Primary hybridoma cell lines contain more than one stable clone of antibodies. Thus, because primary hybridoma cell lines contain more than one stable clone of antibodies, the rejection under 112, 1st paragraph, written description for inadequate showing of possession for a claimed genus of monoclonal antibodies is proper.

6. Claims **1-10 and 19-21** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to the rejection, Applicant submits that a deposit of the biological material designated mAb 1D9 has been fully addressed earlier.

Applicant's submission has been considered, however, it is not sufficient to overcome this rejection. The deposit made by Applicant is a cell line, PTA-4837, that

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may be used to produced the claimed monoclonal antibody. [Lines 14-15, page 4] The deposit made is not the monoclonal antibody itself, as asserted by Applicant. In this case, the cell line deposited by Applicant is a primary hybridoma cell line that contain more than one stable clone of antibodies, rather the single clone that is representative of mAb 1D9. Hence, until any teachings, provided by way of a declaration or a deposition that would enable the skilled artisan to recognize the specifically claimed antibody, the skilled artisan would not be able to make any antibodies that are encompassed by the claimed invention.

As previously noted, the invention appears to employ novel biological materials, specifically monoclonal antibodies, mAb 1D9. Since the biological materials are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. In the instant, while a method for making the antibodies, including of those identified as mAb 1D9 is provided in the specification, however, it is found that a deposit of such biological material is necessary for the specification fails to set forth any structural characteristics known to mAb 1D9. In the absence of any teachings pertaining to the structural characteristics of monoclonal antibodies identified as mAb 1D9, the skilled artisan would not be able to make monoclonal antibodies identified as mAb 1D9. Hence, the biological materials are not so obtainable in the absence of a deposit or additional guidance from the specification. In the instant, the requirements of 35 U.S.C § 112 may be satisfied by a deposit of biological materials. The specification does not disclose a repeatable process to obtain the biological materials and it is not apparent if the

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biological materials are readily available to the public. Applicant may make a deposit at an acceptable depository, which 37 CFR 1.803 provides as

(a) A deposit shall be recognized for the purposes of these regulations if made in:

(1) any International Depositary Authority (IDA) as established under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, or

(2) any other depository recognized to be suitable by the Office.

If the deposit is not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney or record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last requires or from the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of the deposit will be made (see 37 C.F.R. § 1.807); and

(e) the deposit will be replace if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. § 2400 in general, and specifically to

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§ 2411.05, as well as to 37 C.F.R § 1.809(d), wherein it is set forth that “the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination.” The specification should be amended to include this information, however Applicant is cautioned to avoid the entry of new matter into the specification by addition any other information. Finally, Applicant is advised that the address of the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection

10801 University Boulevard

Manassas, VA 20110-2209

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 19-21 remain rejected under 35 U.S.C. 102(b) as being anticipated by O'Connor et al.¹

In response to the rejection, Applicant amended the claims, however, it remains that the claims are directed to a hybridoma cell line.

¹ O'Connor et al., U.S. Patent No. 5177014, published January 05, 1993.

As noted, while the Office notes that the preamble of the claims require that the hybridoma cell line be that is suitable for obtaining monoclonal antibodies specific for an epitope unique to an inactivated FIV-encoded glycoprotein. However, upon careful review of the preamble to determine if it recites structural limitation(s) or is merely a statement of purpose or use, it is found that the stated preamble is merely a statement of purpose or use. Hence, the claims remain to be directed to only a hybridoma cell line that can be used for obtaining monoclonal antibodies specific for an epitope unique to an inactivated FIV-encoded glycoprotein.

In the instant case, O'Connor et al. teaches a hybridoma cell line that is suitable for obtaining monoclonal antibodies, specifically, monoclonal antibodies to feline immunodeficiency virus (FIV). [Lines 66, column 4 to line 56, column 5, in particular.] The hybridoma cell line of O'Connor could also used for obtaining monoclonal antibodies specific for an epitope unique to an inactivated FIV-encoded glycoprotein. Hence, O'Connor et al. teaches the claimed invention. Thus, O'Connor et al. anticipates the claimed invention. For additional guidance relating to the effect of preambles, see MPEP § 2111.02 [R-3].

To overcome this rejection, it is suggested that Applicant amend the claim(s) to include the limitation of the allowable subject matter encompassed by claim 22, which remains to be free of the art.

Conclusion

9. Claims 1-10 and 19-21 stand rejected. Claim 22 remains to be free of the art. Thus, should Applicant would like to proceed with the allowance of the subject matter

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encompassed by claim 22, Applicant should contact the Office, Examiner Emily Le, 571 272 0903.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903.

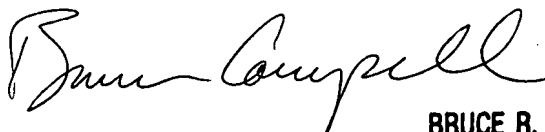
The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bruce R. Campell
Supervisory Patent Examiner
Art Unit 1648

/E.Le/



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